UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF LOUISIANA

SHREVEPORT DIVISION

CHARLES DAVID ROUSSEAU

versus

CIVIL ACTION NO. 06-0517
JUDGE S. MAURICE HICKS, JR.

DEPUY ORTHOPAEDICS, INC. and
HOWMEDICA OSTEONICS CORP.

MEMORANDUM RULING

Before the court is a motion for summary judgment filed by defendant Howmedica Osteonics Corp. ("Howmedica"). See Record Document 25[1]. For the reasons set forth below, Howmedica's motion for summary judgment is **GRANTED**.

I. Background

A. Facts.

On January 23, 2004, plaintiff Charles David Rousseau ("Rousseau") underwent knee replacement surgery. The surgeon implanted two products manufactured, marketed, and sold by defendant DePuy Orthopaedics, Inc. ("DePuy"), and secured them using Simplex bone cement ("Simplex") which is manufactured by Howmedica. Rousseau says that shortly after the surgery, he began to experience excruciating pain in his leg and knee.

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[1]The "Amended Memorandum In Support Of Howmedica Osteonics Corp.'s Motion For Summary Judgment" (Record Document 38) is considered instead of the original memorandum in support attached to the motion for summary judgment (Record Document 25).

In March 2005, surgeons operated on his leg and found that the artificial knee had failed and required replacement.

On March 1, 2006, Rousseau filed suit against DePuy and Howmedica in state court. See Record Document 1. Rousseau claims that he relied upon Howmedica's implied and express warranties that Simplex was safe and durable and would not deteriorate or fail within a reasonable number of years, if ever. See id. He also alleges that Simplex failed because of defective manufacturing and because it was not fit for its intended use. See id. The defendants removed the case to this court. Howmedica then filed the instant motion for summary judgment urging the court to find that Rousseau's state law claims are preempted by federal law and should be dismissed.

B. History of Simplex Bone Cement and the Medical Device Amendments.

Simplex has been used in joint replacement surgeries since the late 1960's. See Record Document 38. It was reviewed and approved by the FDA between 1969 and 1971 through the New Drug Application ("NDA") process. See id. Simplex is approved by the Food and Drug Administration ("FDA") for surgeries for total hip, knee, shoulder, and elbow replacement and repair of pathological fractures. See id. The NDA process required Howmedica to provide the FDA with a body of information to establish the safety and effectiveness of Simplex. See id. The approval required, among other things, completion of clinical trials, long term toxicity and carcinogenicity studies, and animal trials. See id. All of the product labeling, including the package insert and external package labeling, either was drafted by the FDA or required the FDA's approval. See id. The NDA for

Simplex was submitted to the FDA in February of 1971, and the drug was approved for use the following October. See id.

Congress passed the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetics Act in 1976. See id. The MDA places each medical device into one of three classes depending on the degree of risk the device poses to the public. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 476, 116 S.Ct. 2240, 2246 (1996), citing 21 U.S.C. §§ 360c-360k. Devices are designated to Class I and subject only to minimal regulation by "general controls" if they present no unreasonable risk of illness or injury. See Medtronic, 518 U.S. at 476-477. Class II devices are potentially more harmful than Class I and, although they can be marketed without prior approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." See id. at 477. Class III is reserved for devices that "either presen[t] a potential unreasonable risk of illness or injury, or which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." See id. (internal marks omitted). The manufacturer of a new Class III device must provide the FDA with a "reasonable assurance" that the device is both safe and effective through the rigorous premarket approval ("PMA") process before the device may be introduced to the market. See id.

Simplex and similar devices that were classified and approved as new drugs through the NDA process, prior to the enactment of the MDA, were described as "transitional devices." See Record Document 38. The devices were automatically designated as Class III medical devices under the MDA. See id. Such devices were deemed to have PMA

approval. See 21 U.S.C. § 360j(l)(3)(A). Simplex was regulated by the FDA as a Class III device from 1976 until 2002, when it was reclassified to Class II. See Record Document 38.

C. Disputed Material Facts.[2]

The parties agree that during the period that Simplex was classified as a Class III product, the FDA required that specific labeling and packaging be included with each Simplex package. However, they disagree over whether these requirements continued after Simplex was reclassified to Class II. Rousseau argues that because Simplex was reclassified in 2002, it is no longer under a continuing obligation to provide information to the FDA on a regular basis, and any changes in the product or its packaging are no longer required to be approved by the FDA. He alleges that the packaging and packaging inserts are no longer regulated by the FDA.[3] The parties agree that neither the packaging nor any other aspect of Simplex has changed since the product's reclassification.

The parties also agree that Siobhan Cleary ("Cleary") serves as quality manager over Simplex and that the control number of the Simplex used in Rousseau's surgery is RKK409. However, the parties disagree over whether Cleary's affidavit qualifies as admissible summary judgment evidence. In her affidavit, Cleary states that the Simplex used in Rousseau's surgery "was manufactured subject to and in strict accordance with

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[2]See Howmedica's Statement Of Undisputed Material Facts, Record Document 25, and Rousseau's Statement in Response, Record Document 40.

[3]This assertion forms the basis of Rousseau's argument that since the FDA no longer regulates every detail of Simplex and its packaging, a requirement imposed by a state law claim will not conflict with federal requirements, and state law claims should therefore not be preempted. See Record Documents 40, 50.

manufacturing and quality control procedures approved by the FDA." Record Document 25. She also states that there was no defect in the Simplex at issue, and that the Simplex was "distributed in packaging and with package inserts approved and required by the FDA." Id. Rousseau contends that these statements constitute expert opinions which Cleary is not qualified to make, and also that the statements are conclusory and lack foundation.

II. Law and Analysis

A. Summary Judgment Standard.

Summary judgment is proper pursuant to Rule 56 of the Federal Rules of Civil Procedure "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986). "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 263 (5th Cir. 2002). If the movant demonstrates the absence of a genuine issue of material fact, "the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial." Littlefield v. Forney Indep. Sch. Dist., 268 F.3d 275, 282 (5th Cir. 2001). Where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the nonmovant, then summary judgment should be granted. See Alton v. Tex. A&M Univ., 168 F.3d 196, 199 (5th Cir. 1999).

B. Preemption Analysis.

Howmedica claims that because Simplex was approved through the rigorous PMA process, every detail of Simplex and its packaging has been approved by the FDA. Therefore, Howmedica argues, state law claims alleging that these specifications are inadequate would conflict with the FDA's determination and are therefore preempted by federal law. Rousseau asserts that because Simplex has been reclassified to Class II, the FDA requirements are not currently applicable to Simplex and therefore cannot conflict with requirements that could be imposed by state claims.

Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." Medtronic, 518 U.S. at 474 (citing the preamble to the Medical Device Amendments of 1976, 90 Stat. 539.). The MDA's preemption provision, 21 U.S.C. § 360k(a), governs the extent to which the MDA preempts state law. It reads:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. Id.

The FDA has promulgated regulations interpreting section 360k, which state:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to the specific [FDA] requirements. 21 C.F.R. § 808.1(d).

The Fifth Circuit Court of Appeals, in a case involving a device approved through the PMA process, held that section 360k preempted the state law liability claim. See Stamps v. Collagen Corp., 984 F.2d 1416, 1422 (5th Cir. 1993). Later, the Supreme Court, in its 1996 opinion, Lohr, held that a product liability claim was not preempted under section 360k. See Medtronic, 518 U.S. at 477. In Martin v. Medtronic, Inc., 254 F.3d 573, 577 (5th Cir. 2001), the Fifth Circuit examined the Supreme Court's decision in Lohr and discussed the decision's effect on the Fifth Circuit's prior holding in Stamps. The Fifth Circuit found that Lohr involved a device approval process far less specific and rigorous than the PMA process. See Martin, 254 F.3d at 575. In Lohr, the device was approved through the § 510(k) notification process, which is an exception to the more demanding PMA process. See id. at 576. The Supreme Court even noted "[t]he § 510(k) notification process is by no means comparable to the PMA process." Id. at 577 (citing Medtronic, 518 U.S. at 478-79.) Based upon its finding that the PMA process distinguished Stamps from Lohr, the Fifth Circuit held that the Supreme Court did not overrule its prior holding in Stamps regarding PMA-approved products. See Martin, 254 F.3d at 580.

1. The Supreme Court's Decision in Lohr.

In Lohr, a woman claimed she was injured when her pacemaker failed. See Medtronic, 518 U.S. at 480-81. She and her husband brought claims against Medtronic. See id. at 481. In a plurality decision, the Supreme Court analyzed whether the claims, brought under Florida state law, were preempted by the MDA's section 360k preemption provision. See id. at 481-82. After extensive analysis, the Court held that none of the Lohrs' claims were preempted. See id. at 502.

The Court emphasized the fact that the pacemaker at issue was approved after the manufacturer submitted a premarket notification, a process also known as a section 510(k) process. See id. at 478. Through this process, if the FDA concludes on the basis of the premarket notification that the device is substantially equivalent to a pre-existing device, the device can be marketed without further regulatory analysis. See id. The Court stated that the section 510(k) process, which typically takes about 20 hours to complete, is by no means comparable to the PMA process which requires 1,200 hours. See id. at 478-79.

The Supreme Court then analyzed the MDA's preemption provision. The opinion, written by Justice Stevens, states that the interpretation is not made in a vacuum but rather is informed by two presumptions about the nature of preemption: first, the presumption that Congress does not cavalierly preempt state-law causes of action, and second, that "[t]he purpose of Congress is the ultimate touchstone in every preemption case." See id. at 485 (internal marks omitted). At this point in the analysis, Justice Stevens continued writing the opinion, but was joined only by Justice Kennedy, Justice Souter, and Justice Ginsberg. See id. at 474. He stated that it was "implausible" to believe that the plain language preempts all state law causes of action brought by an injured plaintiff against a manufacturer of a medical device. Id. at 486-87. He reasoned that because there is no private cause of action contained in the MDA, if the preemption section had such effect, it would bar most, if not all, relief for those injured by defective medical devices. See id. at 487. If Congress had intended to preempt all common-law causes of action, Justice Stevens reasoned, it could have easily stated that it precluded any "remedy" rather than using the word "requirement" as it did. See id. He rejected the defendant's argument that

the word "requirement" "clearly signaled [Congress's] intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices." Id. at 489.

Justice Stevens also stated that differences between section 360k and a statute the Court considered earlier in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S.Ct. 2698 (1992), further convinced him that in enacting the section, "[Congress] was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." Medtronic, 518 U.S. at 489. He further reasoned that none of the exemptions from the preemption statute that the FDA has granted even remotely resemble common-law claims, leading him to believe Congress did not intend to include common-law claims within the scope of the preemption statute. See id. at 489-90. Congress's primary concern in passing the MDA, he wrote, was protecting the safety of those who use medical devices, not protecting the industry. See id. at 490-91. After examining the Committee Reports, hearings, and debates surrounding the passage of the MDA, Justice Stevens found that Congress did not even hint that it intended a "sweeping preemption of traditional common-law remedies against manufacturers and distributors of defective devices." Id. at 491. He decided that such silence, along with the less-than-precise language in section 360k, indicates that at least some common-law claims against manufacturers may be maintained. See id.

Justice Stevens then analyzed each of the Lohrs' claims to determine whether they were preempted by federal law. He decided that the "substantial equivalence" designation for products approved through the section 510k process did not preempt the Lohrs' negligent design claims. See id. at 494. As to the claims that the product did not meet

standards equivalent to the federal requirements, he found that nothing in section 360k denies the state the right to provide a traditional damage remedy for violations of duties that parallel the federal requirements.[4] See id. at 495.

The Lohrs' final claims were for negligent manufacturing and labeling. See id. at 497. The Lohrs argued that Medtronic's preemption assertion should be rejected in full because the only requirements imposed on the pacemaker were general and not specifically applicable to the particular device. See id. at 497-98. Justice Stevens found that the Lohrs' theory was supported by the FDA regulations, which provide that state requirements are only preempted when specific counterpart regulations or other specific requirements applicable to the device are established by the FDA. See id. at 498. He stated that "[t]he statute and regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly preempted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations." Id. at 500.

After performing such a comparison, Justice Stevens concluded that the Lohrs' claims were not preempted because the federal requirements established were general and also because the general state common-law requirements that would apply in the case were not specifically developed with respect to medical devices. See id. at 501. The state common-law claims for negligent manufacturing and failure to warn, Justice Stevens found, imposed a general duty on every manufacturer and were not the kinds of requirements that

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[4]In a footnote, Justice Stevens stated that "the agency permits manufacturers of devices that have received PMA to make certain labeling, quality control, and manufacturing changes which would 'enhance [ ] the safety of the device or the safety in the use of the device' without prior FDA approval." Id. at 497 n. 16.

Congress and the FDA feared would interfere with the federal regulators' ability to enforce specific federal requirements. See id. These claims impose the general duties to use due care to avoid foreseeable dangers in a product and to inform users and purchasers of the potential risks involved with use of the products, Justice Stevens explained. See id. He even stated that given the device specificity required by section 360k, "it is apparent that few, if any, common-law duties have been preempted by this statute." Id. at 502. "It will be rare indeed," he continued, "for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.'" Id. at 503 (citing 21 C.F.R. § 808.1(d)(6)(ii) (1995)).

Justice Breyer concurred with the ruling, but disagreed with the plurality's analysis of the MDA's preemption section. See id. Breyer wrote that "one can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." Id. at 504. He further stated that he did not join because he was not convinced that "future incidents of MDA preemption of common-law claims will be 'few' or 'rare.'" Id. at 508.

Justice O'Connor concurred in part and dissented in part, and was joined by the Chief Justice, Justice Scalia, and Justice Thomas. See id. at 509. She wrote that the plurality's conclusion that common-law claims are almost never preempted was "bewildering and seemingly without guiding principle." Id. Justice O'Connor wrote that a fair reading of section 360k indicates that common-law claims should be preempted "to the extent that their recognition would impose 'any requirement' different from, or in addition to, [Food, Drug, and Cosmetics Act] requirements applicable to the device." Id. at 512.

She also stated that she did not agree with the Court's interpretation of section 360k that imposes an additional requisite of specificity. See id. at 513. Justice O'Connor concluded that "the statutory language does not indicate that a 'requirement' must be 'specific,' either to preempt or be preempted" but rather that "a state common-law claim is preempted if it would impose '*any requirement*' 'which is different from, or in addition to,' any requirement applicable to the device under the [Food, Drug, and Cosmetics Act]." Id. at 514 (emphasis added).

2. The Fifth Circuit's Analysis of the Lohr Decision.

After Lohr, the Fifth Circuit was forced to analyze whether its holding in Stamps had been overruled. In Martin, the Fifth Circuit considered a device that was approved through the FDA's rigorous PMA process and not the far less demanding section 510k process, as in Lohr. See Martin, 254 F.3d at 575. The Fifth Circuit determined that its earlier decision in Stamps, where it held that section 360k preempted the state products liability claims when the device manufacturer complied with the FDA's PMA process, remained binding precedent and was not entirely overruled by the fractured Supreme Court in Lohr. See id. The court explained that a panel of the Fifth Circuit could only overrule a prior panel decision if "'such overruling is unequivocally directed by controlling Supreme Court precedent.'" Id. at 577 (citing U.S. v. Zuniga-Salinas, 945 F.2d 1302, 1306 (5th Cir. 1991)). The court stated that because only parts of Justice Steven's opinion in Lohr were joined by the majority, it was difficult to determine the final meaning of Lohr. See Martin, 254 F.3d at 579. The Fifth Circuit concluded that the plurality opinion in Lohr did not have the effect

of overruling Stamps, and therefore the Martin panel did not have the authority to do so either. See id. at 580.

The Fifth Circuit then examined each finding in Stamps to determine the extent to which each was affected by the Lohr decision. First, it found that its decision that state tort suits *can* constitute specific state requirements for the purposes of preemption was not overruled by Lohr. See id. at 581 (emphasis added). Second, the court considered its holding that common-law tort claims challenging the safety or effectiveness of a device create specific requirements under state law. See id. at 583. The court found that Lohr did not specifically overrule this holding, but that after Lohr, the court should turn its focus to "whether the specific requirements imposed by those common law duties threaten to interfere with specific federal requirements." Id. Third, the court examined its holding that state tort causes of action are requirements "different from, or in addition to" the PMA process. Id. As to this issue, the court found that Lohr allows for state actions that parallel federal requirements, overruling Stamps as to that particular issue but not as it applied in the case before the court. See id. Last, the court determined that Lohr did not overrule its holding in Stamps that the "PMA process imposed specific federal requirements as to labeling, manufacturing and design for the purposes of preemption." Id. The court stated that Lohr's holding on the issue only applied to devices approved by the section 510k process and could not be extended to devices approved through the PMA process. See id. at 584.

The court then applied these findings to the Martin dispute. It found that the design of the device, the labeling, and the manner of manufacturing were approved by the FDA

through the PMA process and the claims were therefore preempted. See id. at 584-85. The court also affirmed the district court's determination that claims that the device did not comply with the PMA process were not preempted. See id. at 585.

The Fifth Circuit further clarified its Martin analysis in Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919 (5th Cir. 2006). The court stated that this circuit uses the Martin/Lohr test to analyze products liability claims against PMA-approved devices. See id. at 930. The test requires a court to analyze the claims and determine whether the duties enforced by such claims would threaten the federal duties imposed by the PMA process. See id. at 930. The court found that the negligent design and defective design claims were preempted because the FDA studied and approved the device's design through the PMA process. See id. at 930. The FDA also approved the labeling, warnings, instructions, and training process for the device during the PMA process, therefore, any claims of inadequacy in any of these areas were also preempted. See id. at 931.

The plaintiff in Gomez next argued that her warranty claims should not be preempted because after the completion of the PMA, the manufacturer acquired additional information about the risks associated with the product but did not provide updated warnings. See id. The court stated that because the manufacturer had an ongoing obligation to the FDA to report new information obtained after the approval of the device, any related state law claims would interfere with the federal scheme and were preempted. See id. at 931-32. The court also found that a claim for the breach of any express warranties provided under Louisiana law would also be preempted because the duties imposed by such claims were potentially inconsistent with the federal regulatory scheme.

See id. at 932. The only claim that the court found was not preempted was a defective manufacturing claim alleging that the device did not comply with the FDA approved specifications. See id.

C. Preemption Analysis in the Instant Case.

Howmedica asserts that it is entitled to summary judgment because Rousseau's state law claims conflict with federal requirements imposed by the FDA, and are therefore preempted. Simplex was approved through the rigorous NDA process, which Howmedica alleges is even more stringent than the PMA process. Furthermore, Howmedica argues that Simplex has since been regulated as a PMA-approved product, which has required that information be continually provided to the FDA and that all changes to the product be approved. Howmedica claims that both the Supreme Court and Fifth Circuit focus the preemption analysis on the approval process the product underwent. Howmedica urges that Simplex should be treated as all other products approved through the PMA process, and that state law claims should be preempted.

Rousseau claims that Simplex is not currently governed by the strict FDA requirements generally applicable to the Class III devices in the cases Howmedica cites, and that Simplex should therefore not be treated in the same way as these Class III devices. He also argues that any requirements that will be imposed if his claims are successful will not conflict with any FDA regulations *currently* applicable to Simplex as a Class II product. He repeatedly asserts that Howmedica cannot cite one case in which a court has held that claims against a Class II device were preempted as extensively as they are for PMA-approved Class III devices. Rousseau also argues that even if Simplex is

treated in the same manner as Class III devices, the facts he alleges encompass a claim that Simplex does not comply with FDA requirements, which is not preempted.

Unlike the devices at issue in the cases examined by the Supreme Court and the Fifth Circuit, Simplex was approved through the NDA process before the passage of the MDA and the establishment of the PMA process. However, the MDA provides that such devices are deemed to have completed the PMA process. See 21 U.S.C. § 360j(l)(3)(A). Since Simplex is deemed to have been approved through the PMA process, this court will analyze the claims accordingly.

In performing the preemption analysis, both the Supreme Court and the Fifth Circuit concentrate not on the product's classification, but rather on the process the product underwent in order to obtain FDA approval. See Medtronic, 518 U.S. at 493-94, Martin, 254 F.3d at 575; and Gomez, 442 F.3d at 930. This is evidenced by the fact that the Supreme Court in Lohr determined that even though the product was a Class III product, because it was approved through the section 510k process, the claims were not preempted. See Medtronic, 518 U.S. at 478-79. Although the Supreme Court has not decided a claim involving a product approved through the PMA process, the Fifth Circuit has held that such claims are preempted. See Martin, 254 F.3d at 575; See also Gomez, 442 F.3d at 930. Even though the Fifth Circuit has not ruled on a case in which a PMA-approved product was reclassified to Class II, this court holds that in such case, the approval process is key to the preemption analysis. The court finds that the reclassification of Simplex to Class II in 2002 did not cause Simplex to automatically lose the protection from suit it earned when granted approval through the PMA process.

Rousseau does not dispute that since Simplex was reclassified in 2002, no changes have been made to the product, the manufacturing process, or the labeling. See Record Document 40. Therefore, every aspect of the package of Simplex used in Rousseau's surgery had been approved by the FDA, just as it would have been had Simplex remained in Class III. None of the evidence suggests that any changes had occurred in any of the information used in the FDA's approval of Simplex, nor does it suggest that new information had become available that might have changed the FDA's determination. Accordingly, the preemption analysis for the Simplex used in Rousseau's surgery should be the same as for other devices approved through the PMA process, regardless of the fact that Simplex was reclassified.

The Fifth Circuit has ruled that section 360k preempts most state products liability claims when the product was approved through the PMA process. Martin, 254 F.3d at 575. The Martin/Lohr test, which compares the duties imposed by state law claims to the duties imposed by the FDA, is used in the Fifth Circuit to determine if claims are preempted. See Gomez, 442 F.3d at 930.

1. Martin/Lohr Analysis of Rousseau's Claims.

Rousseau's claims consist of the following: breach of implied warranties, breach of express warranties, and defective manufacture because the product was not fit for intended use. See Record Document 1. The Martin/Lohr test requires the court to examine each claim separately to determine which claims, if any, are preempted. See Gomez, 442 F.3d at 930.

a. Breach of Express and Implied Warranties.

The Fifth Circuit has held that because the labeling and warnings are approved by the FDA through the PMA process, the duties arising under the Louisiana breach of warranty statute are potentially inconsistent with the regulatory scheme, and a breach of express warranty claim is therefore preempted. See Gomez, 442 F.3d at 932. The court based the decision on its determination that the Louisiana breach of express warranty statute goes beyond merely enforcing the federal requirements. See id. The court did not specifically decide the issue of Louisiana implied warranty claims. However, the FDA has thoroughly examined the manufacturing process, the safety, and the labeling of every PMA-approved product. See Martin, 254 F.3d at 584-85. A determination that even though the product complies with the FDA requirements, it has a problem causing it to breach an implied warranty, would impose requirements different from or in addition to those imposed by the FDA. Therefore, the court finds that the only warranty claims that will not be preempted are those based on the claim the product did not comply with the FDA requirements. Accordingly, because the FDA approved Simplex's labeling and warnings, this court holds that Rousseau's breach of express and implied warranties claims are preempted to the extent the duties they impose do not parallel the duties imposed by the FDA.

b. Defective Manufacture.

Rousseau claims that the Simplex used in his surgery failed due to its defective manufacture in that it was not fit for its intended use. The Fifth Circuit has held that a defective manufacturing claim under Louisiana law is preempted because the FDA

approves all aspects of the manufacturing during the PMA process. Gomez, 442 at 932-33. The FDA has determined through this process that Simplex is fit for its intended use. See id. The only claims that will survive preemption are claims that the device deviated from the FDA-approved specifications. See id. at 933. Therefore, Rousseau's defective manufacture claims are also preempted except to the extent they are based on an assertion that the Simplex used in Rousseau's surgery deviated from the FDA-approved specifications.

c. Noncompliance with FDA-Approved Specifications.

Howmedica argues that since Rousseau did not include in his complaint a claim that the Simplex used in his surgery did not comply with the FDA requirements, that he cannot now do so. In response, Rousseau argues that his complaint encompassed such claims and that a specific statement of such claim is not required since the complaint was filed in a Louisiana state court which requires only fact pleading. This court finds that a breach of express warranty claim, a breach of implied warranty claim, and a defective manufacturing claim could each be based upon an assertion that the product's failure to comply with the FDA requirements caused the injury.

The next step in the analysis is the determination of whether Rousseau has met the necessary burden of proof to survive summary judgment. If Howmedica demonstrates the absence of a genuine issue of material fact, Rousseau must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial. Littlefield v. Forney Indep. Sch. Dist., 268 F.3d 275, 282 (5th Cir. 2001). Howmedica has introduced an affidavit by its quality control manager, Cleary, in which she asserts that she has reviewed

the business documents concerning the manufacture of the Simplex used in Rousseau's surgery, and that nothing in the documents suggests that this batch of Simplex deviated from the FDA approved specifications.[5] See Record Document 25. Rousseau argues that Cleary is not an expert who is qualified to determine whether a defect existed in Simplex. However, this court determines that she is qualified, as quality manager, to state that there is no evidence in Howmedica's records showing that FDA-approved procedures were not followed and that there is no evidence that the batch of Simplex did not comply with the FDA's standards. Although her opinions are not conclusive on the issue of whether a defect existed, her statements alone support Howmedica's contention that there was no defect in the Simplex used in Rousseau's surgery and that it complied with the FDA approved specifications. Cleary's observation that there is no evidence of a defect in Howmedica's records is sufficient and the court determines she is qualified to make such an observation. Therefore, the determination of whether Cleary is an expert qualified to give her opinion on the ultimate issue of whether a defect existed need not be decided.[6]

Rousseau has provided no evidence in rebuttal, nor he has even articulated any evidence he expects to discover that will support his claims. He simply states that it is too early in the case and that he has not had time to discover any supporting evidence. Rule 56(f) of the Federal Rules of Civil Procedure provides that if the court finds that the party cannot present evidence essential to oppose the motion for summary judgment the court

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[5]The documents to which Cleary refers are attached to her affidavit, and she certifies that they are true and correct copies of the business records.

[6]Rousseau also alleges that the exhibits attached to Howmedica's response to Rousseau's opposition are improper for various reasons. The issue need not be resolved here because the court did not consider the exhibits in making this decision.

may deny the motion or may order a continuance to allow the party to obtain the additional evidence. However, "[t]o obtain a continuance in accordance with Rule 56(f) . . . , a party must specifically explain both why it is currently unable to present evidence creating a genuine issue of fact and how a continuance would enable the party to present such evidence." Liquid Drill, Inc. v. U.S. Turnkey Exploration, Inc., 48 F.3d 927, 930 (5th Cir. 1995). "A Rule 56(f) motion must demonstrate . . . how the additional discovery will likely create a genuine issue of material fact and a district court does not abuse its discretion in denying such a motion where it lacked specificity in identifying the needed discovery." Johnson v. Deep E. Tex. Reg'l Narcotics Trafficking Task Force, 379 F.3d 293, 308 (5th Cir. 2004)(citing Krim v. Banc Tex. Group, Inc., 989 F.2d 1435, 1442 (5th Cir.1993)(internal marks omitted)). Although Rousseau states that he cannot currently present evidence because the case was just filed, he has not identified any potential evidence that he believes he can discover if given time. He has not explained how he *could*, if given more time, introduce any evidence that the Simplex did not comply with FDA specifications. Therefore the court will not grant Rousseau the relief provided by Rule 56(f). Accordingly, the court finds that Rousseau has not met the evidentiary burden necessary to survive Howmedica's motion, and that summary judgment must therefore be granted.

III. CONCLUSION

Based on the foregoing analysis, Howmedica's motion for summary judgment is **GRANTED**. See Record Document 25. All claims by Rousseau against Howmedica are **DISMISSED WITH PREJUDICE.**

An order consistent with the terms of this Memorandum Ruling shall issue herewith.

THUS DONE AND SIGNED at Shreveport, Louisiana, this 13TH day of December, 2006.

S. MAURICE HICKS, JR.
UNITED STATES DISTRICT JUDGE